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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 91.M0105WO8	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IT 02/00680	International filing date *(day/month/year)* 25.10.2002	Priority date *(day/month/year)* 28.05.2002
International Patent Classification (IPC) or both national classification and IPC A61M11/06		
Applicant MEDEL S.P.A. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.12.2003	03.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Zeinstra, H Telephone No. +31 70 340-2824

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 02/00680

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-3, 6-9	as originally filed
4, 5	received on 27.05.2004 with letter of 26.05.2004

Claims, Numbers

1-7	received on 27.05.2004 with letter of 26.05.2004

Drawings, Sheets

1/3-3/3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-7
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I

Basis of the report

1 The amendments filed with the letter dated 26/05/2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
"with a flat end" do not appear to be disclosed as such in the originally filed application. The drawings cannot be considered to be a sound base for such an amendment because they just give a schematic view of an embodiment of the nebulizer.

1.1 Therefore this amendment is not considered for the substantive examination. Therefore, for conformity to the wording of claim 3, the terms "with a flat end" in claim 3 have also not been considered for the substantive examination.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2 Reference is made to the following document:
D1: EP-A-0 620 021 (GLENN JOSEPH G ;A & H PRODUCTS INC (US)) 19 October 1994 (1994-10-19) cited in the application

3 The closest prior art as regard claim 1 is D1.

3.1 The subject matter of this claim differs from this document in that it specifies that "the coating of the body has portions defining extensions of lateral walls of the secondary channel".
In view of this difference, the subject matter of claim 1 is new and therefore meets the requirements of Article 33(2) PCT.

3.2 The feature mentioned at the previous point (the extensions of the lateral walls) serves to "consent a better selection of the particles and to consent the coating body to be maintained in a correct operating position compressed between the secondary channel and the base of the tank in such a way that the coating body can not move and rest firmly engaged between the secondary channel and the

tank". No hint of this feature "extensions of the lateral walls" for the same purpose can be found in the available prior art.
Therefore the subject matter of claim 1 meets the requirements of Article 33(3) PCT.

3.3 The device of claim 1 is industrially applicable, and therefore the requirements of Article 33(4) PCT are met.

3.4 Claims 2 - 7 are dependent on claim 1 and refer to particular embodiments of their subject matter. In view of that, claims 2 - 7 meet the requirements of Article 33(2) to (4) PCT.

<EP-A-0620021 discloses a nebuliser ampoule for aerosol therapy as in the preamble of Claim 1.>

piece with the distributor have some important drawbacks.

First of all, because of the presence of the supports of the platelet, it is impossible to assure a flow of air that is substantially symmetrical relative to the axis of the primary conduit. Consequently, the nebulisation that is formed inside the ampoule is not homogeneous.

In the second place, the presence of the supports forces to construct a single pair of channels for aspirating the medical product. Given the geometry of the distributor and of the activator element, the supports inevitably interfere with at least a pair of channels positioned in correspondence with a diameter of the cone, compromising a correct distribution of the medical liquid inside the flow of air present in the ampoule.

<>

DISCLOSURE OF THE INVENTION.

The aim of the present invention is to eliminate the aforesaid drawbacks making available a nebuliser ampoule provided with an activator element able to assure a primary flow of air, substantially symmetrical relative to the axis of the primary conduit.

Another aim of the present invention is to propose a nebuliser ampoule provided with a distributor element which allows to obtain any number of channels, regardless of the presence of the activator element.

An additional aim of the present invention is to make available a nebuliser ampoule provided with an activator element which does not interfere with the fluid dynamics of the spray in correspondence with the so-called aerosol generation plane, this term defining the space of the ampoule just outside the cone and around it.

Yet another aim of the present invention is to obtain a nebuliser ampoule

provided with means for selecting the dimensions of the particles present in the spray, to improve the therapeutic effect of the medical product dispensed by the ampoule.

Said aims are fully achieved by the nebuliser ampoule, in particular for aerosol therapy, of the present invention, which is characterised by the content of the claims set out below ~~and in particular in that the element for~~ activating the nebulisation is physically separate from the element for distributing the medical product. The term "physically separate" means that the activator element is not made in a single piece with the distributor element and hence is distinct therefrom. However, it would be possible to interconnect the activator element and the distributor element, for instance by means of a snap-on coupling.

In particular, the distributor element comprises at least a nozzle for injecting a primary flow of air inside the ampoule to generate the nebulisation. The distributor element is provided with at least a preferably conical coating body, inserted on the nozzle and provided with at least a channel to convey the ~~medical product from a tank of the ampoule to a nebulisation area.~~

BEST MODE FOR CARRYING OUT THE INVENTION.

These aims and other aims will become more readily apparent from the description that follows of a preferred embodiment illustrated, purely by way of non limiting example, in the accompanying drawing tables, in which:

- Figure 1 shows a partially section front view of an apparatus for aerosol therapy provided with a nebuliser ampoule according to the invention;
- Figure 2 shows a top view of the apparatus of Figure 1;
- Figure 3 shows a lateral view of the ampoule of the apparatus shown in

CLAIMS

1. Nebuliser ampoule (2), in particular for aerosol therapy, of the type ~~comprises:~~ comprising:

- at least a mouthpiece (3) for dispensing a nebulised medical product;
- at least an element (4) for distributing the medical product;
- at least an element (5) for activating the nebulisation,

~~characterised in that the activator element (5) is~~ physically separate from the element (4) for distributing the medical product,

~~2. Nebuliser ampoule as claimed in claim 1, characterised in that~~ the distributor element (4) ~~comprises~~ comprising:

at least a nozzle (6) for injecting a flow of air, called primary flow, inside the ampoule (2), said flow being necessary for generating the nebulisation;

at least a coating body (7) inserted on the nozzle (6) and provided with at least a channel for conveying the medical product from a tank (8) of the ampoule (2) to a nebulisation area;

3. Nebuliser ampoule as claimed in claim ~~2~~ 1, characterised in that the activator element (5) has a portion (5a) having substantially circular section with a flat end and is superposed to the nozzle (6) at a pre-set distance from an outlet (6a) thereof.

~~4. Nebuliser ampoule as claimed in claim 1, characterised in that it~~ comprises means for selecting particles of the nebulisation having predetermined dimensions.

5. Nebuliser ampoule as claimed in claim 1, characterised in that it ~~comprises~~ a supplementary, or secondary, channel (9), for introducing a flow of air, called secondary flow, into the ampoule (2) to increase and refine the

nebulisation of the medical product.

4. ~~6.~~ Nebuliser ampoule as claimed in claim ~~5~~ 1, characterised in that the secondary channel (9) is coaxial to the distributor element (4).

5. ~~7.~~ Nebuliser ampoule as claimed in claim ~~5~~ 1, characterised in that the activator element (5) is made of a single piece with the secondary channel (9).

6. ~~8.~~ Nebuliser ampoule as claimed in claim ~~5~~ 1, characterised in that the secondary channel (9) is provided with lateral walls (9a) which extend below an outlet (6a) of the distributor element (4) or in any case below a plane of generation of the nebulisation.

~~9. Nebuliser ampoule as claimed in claim 8, characterised in that~~ the coating body (7) has portions (7a) defining extensions of ~~the~~ lateral walls (9a) of the secondary channel ~~conduit~~ (9).

~~10. Nebuliser ampoule as claimed in claim 8, characterised in that said~~ lateral walls (9a) define means ~~for selecting~~ particles of the nebulisation ~~having predetermined dimensions.~~

7. ~~11.~~ Nebuliser apparatus, in particular for aerosol therapy, characterised in that it comprises a nebuliser ampoule (2) as claimed in the previous claims.

2. Nebuliser ampoule as claimed in claim 1, wherein the portions (7a) consist of a ring connected to the coating body (7) by means of supporting elements (7b) and the ring is positioned in correspondence with lower ends of the lateral walls (9a),
the lateral walls (9a) together with the ring constituting means for selecting particles of the nebulisation having predetermined dimensions.